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| APPLICATION NO.              | FILING DATE | FIRST NAMED INVENTOR      | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------------|-------------|---------------------------|---------------------|------------------|
| 10/523,445                   | 01/31/2005  | Dominique Louis Surleraux | TIP-0040USNP        | 4396             |
| 27777                        | 7590        | 12/22/2008                | EXAMINER            |                  |
| PHILIP S. JOHNSON            |             |                           | WANG, SHENGJUN      |                  |
| JOHNSON & JOHNSON            |             |                           |                     |                  |
| ONE JOHNSON & JOHNSON PLAZA  |             |                           | ART UNIT            | PAPER NUMBER     |
| NEW BRUNSWICK, NJ 08933-7003 |             |                           | 1617                |                  |
|                              |             |                           |                     |                  |
|                              |             |                           | MAIL DATE           | DELIVERY MODE    |
|                              |             |                           | 12/22/2008          | PAPER            |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/523,445             | SURLERAUX ET AL.    |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Shengjun Wang          | 1617                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 23 September 2008.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-23 is/are pending in the application.

4a) Of the above claim(s) 1-8, 11, 13-15 and 19-23 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 9, 10, 12, 17 and 18 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 8/21/2006.

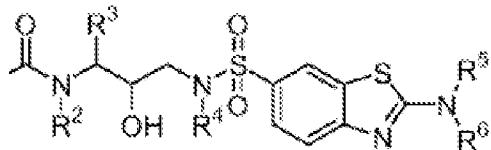
4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_.

**DETAILED ACTION**

1. Claims 1-8 and 19-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, claims 11, 13-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on September 23, 2008.
2. Applicant's election with traverse of invention group IIA, drawn to compound defined by the general formula wherein R1 is hexahydrofuro[2,3-b]furanyl group in the reply filed on September 23, 2008 is acknowledged. Applicants' election is without traverse with respect of groups I and II, but with traverse with respect to A-F. The traversal is on the ground(s) that all the subgroups A-F for R1 are substituents within the bigger inventive scaffold of formula (I). Subdivisional into smaller groups is inconsistent with philosophy of the patent system to have a single invention in a patent. This is not found persuasive because with different substituents herein, the general formula (I) will constitute distinct compounds. Particularly, As shown by the references on the record, that the moiety



3. recited in general formula (I) cannot be considered as inventive technical core feature because such moiety has been known in the art as building block for HIV protease inhibitors, the same purpose herein intended. Compounds with different R1 as herein recited may not be obvious each from the others, absent evidence to the contrary.

Therefore, each of the groups defined by different R1 deserves different search and consideration as to the patentability.

The requirement is still deemed proper and is therefore made FINAL.

Since applicants did not elect a particular compound and since claim 18 recites a single compound, the compound recited in claim 18 is considered as elected species.

***Double Patenting Rejections***

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 9, 10, 12 and 16-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 106-125 of copending Application No. 10/467,609, in further view of Vazquez et al. (US. 5,968,942) and Alexander (WO 96/18605). Claims in ‘609 are directed to compounds essentially the same herein except that the amino group on benzothiazole is derivative to a carbamate moiety. See, particularly claim 125. However, the compound herein claimed would have been viewed as the active

metabolites of the compounds in '609 as carbamate is a well known prodrug for amine. See, pages 2-3 in Alexander. Vazquez et al. further discloses retrovirus protease inhibitors with 2-amino-benzothiazole as a terminal group. See, table 16 in columns 155-160. teaching that compound with the amino group would be similarly useful as those with carbamate.

This is a provisional obviousness-type double patenting rejection.

***Claim Rejections 35 U.S.C. 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

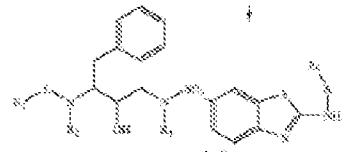
A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 9, 10, 12 and 16-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Surleraux et al. (US 2004/0116485)

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

‘485 teaches and uses the compound recited in claim 18. See, particularly example 4 at page 20, particularly, paragraph [0199], which refers to compound a-8



(page 9)

(R.sub.2=H, R.sub.4=isobutyl, --A--R.sub.6=H and --L--R.sub.1=[[hexahydrofuro[2,3-b]furan-3-yl]oxy]carbonyl).

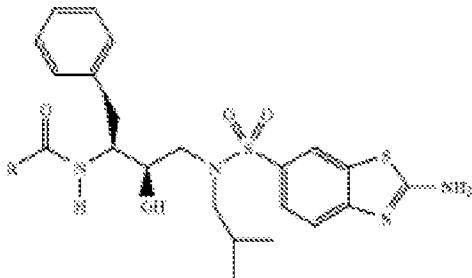
***Claim Rejections 35 U.S.C. 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 9, 10, 12, and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erickson et al. (WO 99/67417, IDS) and Vazquez et al. (US 5,968,942).

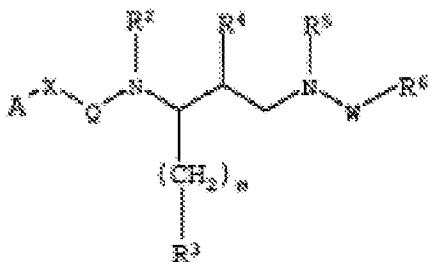
10. Vazquez et al. teaches retrovirus protease inhibitors, particularly as inhibitors of HIV protease having general formula of



wherein R may a variety of different moieties including aromatic, non-aromatic mono and bicyclic rings, See, particularly, the abstract, columns 155-160 and the claims, particularly, claim

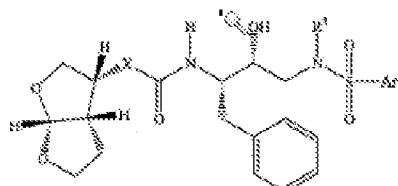
16. Much broader scope of the compounds are also claimed, see, the claims. hexahydrofuro[2,3-b]furanyl group is particularly disclosed as suitable for R. See, particularly, columns 173, 177.

Erickson et al. teaches a retroviral protease inhibitor with a general formula:



A is heterocyclic ring, particularly, hexahydrofuro[2,3-

b]furanyl group, and R6 is aryl or heteroaryl group with at least one substituent, which may be amino groups. See, particularly, the abstract and claim 47. Much narrowed scope of compounds are also claimed which are essentially identical to the compounds herein claimed except the Ar is not 2-aminobenzothiazole groups.



wherein X is O, and R5 is isobutyl. See, claims 51-55.

The cited references do not teach expressly the compound recited in claim 18, which featured a hexahydrofuro[2,3-b]furanyl group at left and 2-aminobenzothiazole at right. However, it would have been *prima facie* obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to make the compound: {3- [(2-amino-benzothiazole-6-sulfonyl)-isobutyl-amino]- 1 -benzyl-2-hydroxypropyl} -carbamic acid hexahydro-furo[2,3-b]furan-3-yl ester.

A person of ordinary skill in the art would have been motivated to make the compound of {3-[(2-amino-benzothiazole-6-sulfonyl)-isobutyl-amino]-1-benzyl-2-hydroxypropyl}-carbamic acid hexahydro-furo[2,3-b]furan-3-yl ester because the instant compound are generically described, and the particular moieties herein, i.e., 2-aminobenzothiazole and hexahydrofuro[2,3-b]furanyl group are expressly taught as useful as building blocks for the protease inhibitors.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shengjun Wang/  
Primary Examiner, Art Unit 1617